

<b>INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		10575193
	Filing Date		2006-10-24
	First Named Inventor	Hattori et al.	
	Art Unit	1645	
	Examiner Name	Michael Edward Sziperka	
Attorney Docket Number		14875-0160US1	

U.S.PATENTS							Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	
	1	5945311		1999-08-31	LINDHOFER et al.		

If you wish to add additional U.S. Patent citation information please click the Add button.

Add

U.S.PATENT APPLICATION PUBLICATIONS							Remove
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	
	1	20090324589		2009-12-31	IGAWA et al.		

If you wish to add additional U.S. Published Application citation information please click the Add button.

Add

FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> j	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	9601653	WO		1996-01-25	THORPE et al.		<input type="checkbox"/>
	2	1510943	EP		2005-03-02	SAITO et al.		<input type="checkbox"/>
	3	1870459	EP		2007-12-26	IGAWA et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10575193
Filing Date		2006-10-24
First Named Inventor	Hattori et al.	
Art Unit	1645	
Examiner Name	Michael Edward Szperka	
Attorney Docket Number	14875-0160US1	

4	09506001	JP	1997-06-17	LINDHOFER et al.	<input type="checkbox"/>
5	9533844	WO	1995-12-14	LINDHOFER et al.	<input type="checkbox"/>
6	9627011	WO	1996-09-06	CARTER et al.	<input type="checkbox"/>
7	9803546	WO	1998-01-29	BOONE et al.	<input type="checkbox"/>
8	2006106905	WO	2006-10-12	IGAWA et al.	<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	SCHMIDT et al., Human Physiology, Moscow, 2:431-436 (1996), and English translation: SCHMIDT et al., "Hemostatis and Coagulation," Human Physiology, R.F. Schmidt, G. Thews (Eds.), Second, Completely Revised Edition, 418-423 [translated by Marguerite A. Biederman-Thorson], Springer-Verlag, 1989	<input checked="" type="checkbox"/>
	2	SCHMIDT et al., Human Physiology, Moscow, 3:764 (1996), and English translation: SCHMIDT et al., "Enzymes of the pancreatic juice," Human Physiology, R.F. Schmidt, G. Thews (Eds.), Second, Completely Revised Edition, 716 [translated by Marguerite A. Biederman-Thorson], Springer-Verlag, 1989	<input checked="" type="checkbox"/>
	3	BLAZAR, "Infusion of Anti-B7.1 (CD80) and Anti-B7.2 (CD86) Monoclonal Antibodies Inhibits Murine Graft-Versus-Host Disease Lethality in Part Via Direct Effects on CD4+ and CD8+ T Cells," J. Immunol., 157:3250-59 (1996)	<input type="checkbox"/>
	4	U.S. EXAMINER ILIA I. OUSPENSKI, USPTO Non-Final Office Action in U.S. App. Ser. No. 10/575,905, mailed June 23, 2010, 10 pages	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10575193
Filing Date	2006-10-24
First Named Inventor	Hattori et al.
Art Unit	1645
Examiner Name	Michael Edward Szperka
Attorney Docket Number	14875-0160US1

5	ADAMS et al., "Humanization of a recombinant monoclonal antibody to produce a therapeutic HER dimerization inhibitor, pertuzumab," Cancer Immunol. Immunother., 55:717-727 (2006)	<input type="checkbox"/>
6	BINZ et al., "Engineering novel binding proteins from nonimmunoglobulin domains," Nat. Biotechnol., 23:1257-68 (2005)	<input type="checkbox"/>
7	BRANDEN and TOOZE, "Recognition of Foreign Molecules by the Immune System," Introduction to Protein Structure, 2d Ed., Garland Publishing, pp. 299-323 (1999)	<input type="checkbox"/>
8	COMPER and GLASGOW, "Charge selectivity in kidney ultrafiltration," Kidney Int., 47:1242-51 (1995)	<input type="checkbox"/>
9	COUTO et al., "Anti-BA46 Monoclonal Antibody Mc3: Humanization Using a Novel Positional Consensus and In Vivo and In Vitro Characterization," Cancer Res., 55:1717-22 (1995)	<input type="checkbox"/>
10	DEEN et al., "Structural determinants of glomerular permeability," Am. J. Physiol. Renal. Physiol., 281:F579-F596 (2001)	<input type="checkbox"/>
11	DEL RIO et al., "An Engineered Penicillin Acylase with Altered Surface Charge Is More Stable in Alkaline pH," Ann. NY Acad. Sci., 799:61-64 (1996)	<input type="checkbox"/>
12	DILLON et al., "Structural and functional characterization of disulfide isoforms of the human IgG2 subclass," J. Biol. Chem., 283(23):16206-15 (2008)	<input type="checkbox"/>
13	EWERT et al., "Stability improvement of antibodies for extracellular and intracellular applications: CDR grafting to stable frameworks and structure-based framework engineering," Methods, 34:184-199 (2004)	<input type="checkbox"/>
14	GHETIE and WARD, "FcRn: the MHC class I-related receptor that is more than an IgG transporter," Immunol. Today, 18:592-598 (1997)	<input type="checkbox"/>
15	GHETIE et al., "Increasing the serum persistence of an IgG fragment by random mutagenesis," Nat. Biotechnol., 15:637-640 (1997)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10575193
Filing Date	2006-10-24
First Named Inventor	Hattori et al.
Art Unit	1645
Examiner Name	Michael Edward Szperka
Attorney Docket Number	14875-0160US1

16	GHETIE et al., "Multiple roles for the major histocompatibility complex class I-related receptor FcRn," Annu. Rev. Immunol., 18:739-766 (2000)	<input type="checkbox"/>
17	GOBBURU et al., "Pharmacokinetics/dynamics of 5c8, a monoclonal antibody to CD154 (CD40 ligand) suppression of an immune response in monkeys," J. Pharmacol. Exp. Ther., 286:925-930 (1998)	<input type="checkbox"/>
18	GOODE et al., "The glomerular basement membrane charge-selectivity barrier: an oversimplified concept?," Nephrol. Dial. Transplant., 11:1714-16 (1996)	<input type="checkbox"/>
19	GRAVES et al., "Molecular modeling and preclinical evaluation of the humanized NR-LU-13 antibody," Clin. Cancer Res., 5:899-908 (1999)	<input type="checkbox"/>
20	GUPTA et al., "Affinity chromatography and co-chromatography of bispecific monoclonal antibody immunoconjugates," J. Biochem. Biophys. Methods, 51:203-216 (2002)	<input type="checkbox"/>
21	HANSON et al., "Catalytic antibodies and their applications," Curr. Opin. Biotechnol., 16:631-636 (2005)	<input type="checkbox"/>
22	HE et al., "Humanization and pharmacokinetics of a monoclonal antibody with specificity for both E- and P-selectin," J. Immunol., 160:1029-35 (1998)	<input type="checkbox"/>
23	HINTON et al., "An engineered human IgG1 antibody with longer serum half-life," J. Immunol., 176:346-356 (2006)	<input type="checkbox"/>
24	ITO et al., "The His-probe method: effects of histidine residues introduced into the complementarity-determining regions of antibodies on antigen-antibody interactions at different pH values," FEBS Lett., 309:85-88 (1992)	<input type="checkbox"/>
25	KASHMIRI et al., "Generation, characterization, and in vivo studies of humanized anticarcinoma antibody CC49," Hybridoma, 14:461-473 (1995)	<input type="checkbox"/>
26		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10575193
Filing Date	2006-10-24
First Named Inventor	Hattori et al.
Art Unit	1645
Examiner Name	Michael Edward Szperka
Attorney Docket Number	14875-0160US1

27	KHAWLI et al., "Improved tumor localization and radioimaging with chemically modified monoclonal antibodies," Cancer Biother. Radiopharm., 11:203-215 (1996)	<input type="checkbox"/>
28	KIM et al., "Antibody Engineering for the Development of Therapeutic Antibodies," Mol. Cells, 20:17-29 (2005)	<input type="checkbox"/>
29	KIM et al., "Chemical modification to reduce renal uptake of disulfide-bonded variable region fragment of anti-tac monoclonal antibody labeled with 99mTc," Bioconjugate Chem., 10:447-453 (1999)	<input type="checkbox"/>
30	KIM et al., "Lowering of pI by acylation improves the renal uptake of 99mTc-labeled anti-Tac dsFv: effect of different acylating reagents," Nucl. Med. Biol., 29:795-801 (2002)	<input type="checkbox"/>
31	KOBAYASHI et al., "The pharmacokinetic characteristics of glycolated humanized anti-Tac Fabs are determined by their isoelectric points," Cancer Res., 59:422-430 (1999)	<input type="checkbox"/>
32	KREUTZ et al., "Efficient bispecific monoclonal antibody purification using gradient thiophilic affinity chromatography," J. Chromatogr. B, 714:161-170 (1998)	<input type="checkbox"/>
33	LINDHOFER et al., "Preferential Species-Restricted Heavy/Light Chain Pairing in Rat/Mouse Quadromas," J. Immunol., 155:219-225 (1995)	<input type="checkbox"/>
34	LOBO et al., "Antibody pharmacokinetics and pharmacodynamics," J. Pharm. Sci., 93:2645-68 (2004)	<input type="checkbox"/>
35	MANZKE et al., "Single-step purification of bispecific monoclonal antibodies for immunotherapeutic use by hydrophobic interaction chromatography," J. Immunol. Methods, 208:65-73 (1997)	<input type="checkbox"/>
36	MARTIN et al., "Crystal structure at 2.8 Å of an FcRn/heterodimeric Fc complex: mechanism of pH-dependent binding," Mol. Cell, 7:867-877 (2001)	<input type="checkbox"/>
37	MARVIN et al., "Recombinant approaches to IgG-like bispecific antibodies," Acta. Pharmacol. Sin., 26:649-658 (2005)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10575193
Filing Date	2006-10-24
First Named Inventor	Hattori et al.
Art Unit	1645
Examiner Name	Michael Edward Szperka
Attorney Docket Number	14875-0160US1

38	MARVIN et al., "Redesigning an antibody fragment for faster association with its antigen," Biochemistry, 42:7077-83 (2003)	<input type="checkbox"/>
39	MERCHANT et al., "An efficient route to human bispecific IgG," Nat. Biotechnol., 16:677-681 (1998)	<input type="checkbox"/>
40	ONDA et al., "Lowering the Isoelectric Point of the Fv Portion of Recombinant Immunotoxins Leads to Decreased Nonspecific Animal Toxicity without Affecting Antitumor Activity," Cancer Res., 61:5070-77 (2001)	<input type="checkbox"/>
41	PAVLINKOVA et al., "Charge-modified single chain antibody constructs of monoclonal antibody CC49: Generation, characterization, pharmacokinetics, and biodistribution analysis," Nucl. Med. Biol., 26:27-34 (1999)	<input type="checkbox"/>
42	PAVLOU et al., "The therapeutic antibodies market to 2008," Eur. J. Pharm. Biopharm., 59:389-396 (2005)	<input type="checkbox"/>
43	PODUSLO et al., "Polyamine modification increases the permeability of proteins at the blood – nerve and blood-brain barriers," J. Neurochem., 66:1599-1609 (1996)	<input type="checkbox"/>
44	RAJPAL et al., A general method for greatly improving the affinity of antibodies by using combinatorial libraries," Proc. Natl. Acad. Sci. USA, 102:8466-71 (2005)	<input type="checkbox"/>
45	RATHANASWAMI et al., "Demonstration of an in vivo generated sub-picomolar affinity fully human monoclonal antibody to interleukin-8," Biochem. Biophys. Res. Commun., 334:1004-13 (2005)	<input type="checkbox"/>
46	REICHERT et al., "Monoclonal antibody successes in the clinic," Nat. Biotechnol., 23:1073-78 (2005)	<input type="checkbox"/>
47	SAL-MAN et al., "Arginine mutations within a transmembrane domain of Tar, an Escherichia coli aspartate receptor, can drive homodimer dissociation and heterodimer association in vivo," Biochem. J., 385:29-36 (2005)	<input type="checkbox"/>
48	SCHAEFFER et al., "The Rat Glomerular Filtration Barrier Does Not Show Negative Charge Selectivity," Microcirculation, 9:329-342 (2002)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10575193
Filing Date		2006-10-24
First Named Inventor	Hattori et al.	
Art Unit	1645	
Examiner Name	Michael Edward Szperka	
Attorney Docket Number	14875-0160US1	

49	SEGAL et al., "Bispecific antibodies in cancer therapy," Curr. Opin. Immunol., 11:558-562 (1999)	<input type="checkbox"/>
50	SHAUL, "Exploring the charge space of protein-protein association: a proteomic study," Proteins, 60:341-352 (2005)	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.